



# UNITED STATES PATENT AND TRADEMARK OFFICE

T

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,633	04/15/2004	Thomas D. Willis	AFMX-P02-201	1327
42145	7590	12/14/2007		
Lisa M. Treannie Morse, Barnes-Brown & Pendleton, P.C. Reservoir Place 1601 Trapelo Road Waltham, MA 02451			EXAMINER STAPLES, MARK	
			ART UNIT	PAPER NUMBER
			1637	
			MAIL DATE	DELIVERY MODE
			12/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/826,633

Applicant(s)

WILLIS ET AL.

Examiner

Mark Staples

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 48-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Finality Withdrawn***

1. The finality of the last Office Action is withdrawn. The prior double patenting rejections made on the instant claims over the claims of Willis et al. (Patent 6,858,412) are withdrawn. However new grounds of rejection are now made. The new grounds of rejection are made in view of Gunderson et al. (United States Patent Application 20030207295 published Nov. 6, 2003, Serial No. 10/264,574 filed on Oct. 4, 2002 and which is a CON of 09/553,993 filed 04/20/2000 ABN which claims benefit of U.S.S.N.s 60/135,123 filed May 20, 1999 and which claims benefits of the following: 60/160,917, filed October 22, 1999; 60/135,051, filed May 20, 1999; 60/161,148, filed October 22, 1999; 60/130,089, filed April 20, 1999; 60/160,027, filed October 22, 1999; and 60/135,053, May 20, 1999).

Claims 48-71 are pending and at issue.

Applicants' arguments filed on 11/23/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Terminal Disclaimer***

2. The terminal disclaimer filed on 11/23/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,858,412 has been reviewed and is accepted. The terminal disclaimer has been recorded.

**Double Patenting Rejections Withdrawn**

3. The rejection of claims 48-54, 56, 57, 60-62, and 64-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,858,412 of Wills et al. is withdrawn. Applicant has overcome this rejection by filing a terminal disclaimer.

4. The rejection of claims 55, 63, 58, and 59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,858,412 of Wills et al. in view of Speel (September 1999) is withdrawn. Applicant has overcome this rejection by filing a terminal disclaimer.

5. The provisional rejection of claims 48-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 16 of copending Application No. 11,152,460 in view of Speel (September 1999) is withdrawn. Applicant's arguments are persuasive. The claims of copending Application No.

11,152,460 have been amended and are not directed to the same or obvious subject matter.

**Double Patenting Rejections Maintained**

6. The provisional rejection of claims 48-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48-72 of copending Application No. 11,335,196 in view of Speel (September 1999) is maintained. Applicant's argument is not persuasive. Examiner finds no record of the copending application being abandoned, as stated by Applicant. As there are new grounds of rejection given below, this rejection is maintained.

7. The provisional rejection of claims 48-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11,375,818 in view of Speel (September 1999) is maintained. Applicant's argument is not persuasive. As there are new grounds of rejection given below, this rejection is maintained.

**New Rejections**

***New Claim Rejections - 35 USC § 112***

8. Claim 63 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 recites the limitation "said step of digesting" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Benefit Claim for Instant Application***

9. The instant application is a continuing application of 09/999,362 filed 10/24/2001, U.S. Patent 6,858,412 which claims benefit of U.S.S.N. 60/242,901, filed October 24, 2000.

***New Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 48-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Gunderson et al. (United States Patent Application 20030207295 published Nov. 6, 2003 which claims the benefit of an earliest filing date of 04/20/1999).

Regarding claims 48 and 69, Gunderson et al. teach methods of detecting one or more nucleic acid target sequences in a sample, the method comprising the steps of: forming one or more closed circular probes (see paragraph 0046 where circular probes are ligated and see also Figures 6 and 7 and their descriptions at paragraphs 0064 and

0065) whenever a first targeting domain and a second targeting domain of any of a plurality of precircle probes hybridize with their respective first target domains and second target domains of the one or more target sequences such that 5' and 3' nucleotides of the respective precircle probes abut one another (see Figure 7A where first primer/probe no. 45 and second primer/probe 50 each having different target domains abut one another, and see paragraph 0047), each precircle probe further having at least a first universal primer site and a cleavage site (see for example paragraphs 0207, 0210, 0219, 0398, 0400, and 04001 each describing a cleavage site on a probe/primer which is inherently universal in a RNA:DNA hybridization complex as described in paragraph 00218);

cleaving the one or more closed circular probes to form cleaved probes;

amplifying cleaved probes using a first universal primer complementary with a first universal primer site (that is, where the primer site is identical in each padlock probe, a type of circular probe, see paragraph 0179 and 0192) to form one or more amplicons (by rolling circle amplification RCA, see 0179); and

detecting the amplicons to detect the one or more nucleic acid target sequences in the sample (see entire publication, especially claims 1 and 11).

Regarding claims 49 and 63 Gunderson et al. teach digesting said precircle by teching where unligate probe including circular probes are digested (see paragraph 110).

Regarding claims 50-52, Gunderson et al. teach barcode sequences for detection (see paragraph 0573) and hybridizing to arrays (entire reference, especially claims 1 and 2).

Regarding claims 53 and 54, Gunderson et al. teach primer sites with identical sequences and at a least second universal primer site by teaching that there may be more than one identical/universal priming site (see paragraph 0047).

Regarding claims 56 and 57, Gunderson et al. teach hybridizing a label probe which can be a directly detected label (entire publication, especially claim 11).

Regarding claims 58 and 59, Gunderson et al. teach secondary detectable labels (see paragraph 0094) which can be a hapten such as biotin (see paragraph 0095).

Regarding claims 60 and 64, Gunderson et al. teach a gap domain by teaching that a gap may exist between the first and second primers (see paragraph 0198).

Regarding claims 61 and 70, Gunderson et al. teach a second universal primer site with a cleavage site between the first and second universal primer sites by teaching: ". . . the signalling probe[/primer] that hybridizes to the target) and a quencher (generally on the detection sequence), with a cleavage site in between" where a capture probe/primer (see paragraph 0400).

Regarding claims 62 and 71, Gunderson et al. making amplicons with a first universal primer and second universal primer complementary to the second universal primer site (see paragraph 0047).

Regarding claims 64-68, Gunderson et al. teach ligating a gap domain and by use of ligase (see paragraph 0420), teach a "gap" of one or more nucleotides (see



paragraph 0066), and where the ligation is used to form a closed circle (see paragraph 0046 where circular probes are ligated and see also Figures 6 and 7 and their descriptions at paragraphs 0064 and 0065).

***New Claim Rejections - 35 USC § 103***

11. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunderson et al. as applied to claim 54 above, and further in view of Carter et al. (1971).

Gunderson et al. teach as noted above.

Regarding claim 55, Gunderson et al. teach digesting using exonucleases and thus removing exonuclease activity (see paragraph 0110).

Regarding claim 55, Gunderson et al. teach do not specifically teach denaturing an exonuclease.

Carter et al. teach denaturing exonuclease by heat (see p. 2504, 2<sup>nd</sup> column, 1<sup>st</sup> full paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the removal of exonuclease activity by the protease degradation of Gunderson et al. by substituting heat denaturation to remove the exonuclease activity as suggested by Carter et al. with a reasonable expectation of success. The motivation to do so is provided by Carter et al. who teach that heat denaturation removed exonuclease activity. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

**Conclusion**

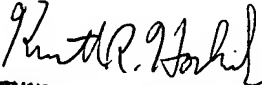
12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples MS  
Examiner  
Art Unit 1637  
December 11, 2007

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER  
12/12/07